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Gordon et al.

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(54) **SECURING A MEDICAL DEVICE TO A VALVE INSTRUMENT**

(71) Applicant: **Radux Devices, LLC**, Omaha, NE (US)

(72) Inventors: **Gregory Gordon**, Omaha, NE (US); **Ryan Balko**, Maple Grove, MN (US); **Anders Olmanson**, Eagan, MN (US); **Travis White**, Zimmerman, MN (US)

(73) Assignee: **Radux Devices, LLC**, Omaha, NE (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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A61M 39/06 (2006.01)

(52) **U.S. Cl.**
CPC ... ***A61M 39/0693*** (2013.01); *A61M 2039/062* (2013.01); *A61M 2039/064* (2013.01)

(58) **Field of Classification Search**
CPC A61M 39/0693; A61M 2039/062; A61M 2039/064
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,853,126	A	12/1974	Schulte
3,998,222	A	12/1976	Shihata
4,316,461	A	2/1982	Marais et al.
4,387,879	A	6/1983	Tauschinski
4,453,933	A	6/1984	Speaker
4,840,613	A	6/1989	Balbierz
4,850,954	A	7/1989	Charvin
4,865,586	A	9/1989	Hedberg
4,976,698	A	12/1990	Stokley
5,031,775	A	7/1991	Kane
5,443,460	A	8/1995	Miklusek
5,538,513	A	7/1996	Okajima
5,647,859	A	7/1997	Lampropoulos et al.

(Continued)

FOREIGN PATENT DOCUMENTS

JP	2003-525660	9/2003
JP	2010-524546	7/2010

(Continued)

OTHER PUBLICATIONS

Japanese Office Action in Application No. JP2016-523205, dated Aug. 27, 2018, 11 pages (with English Translation).

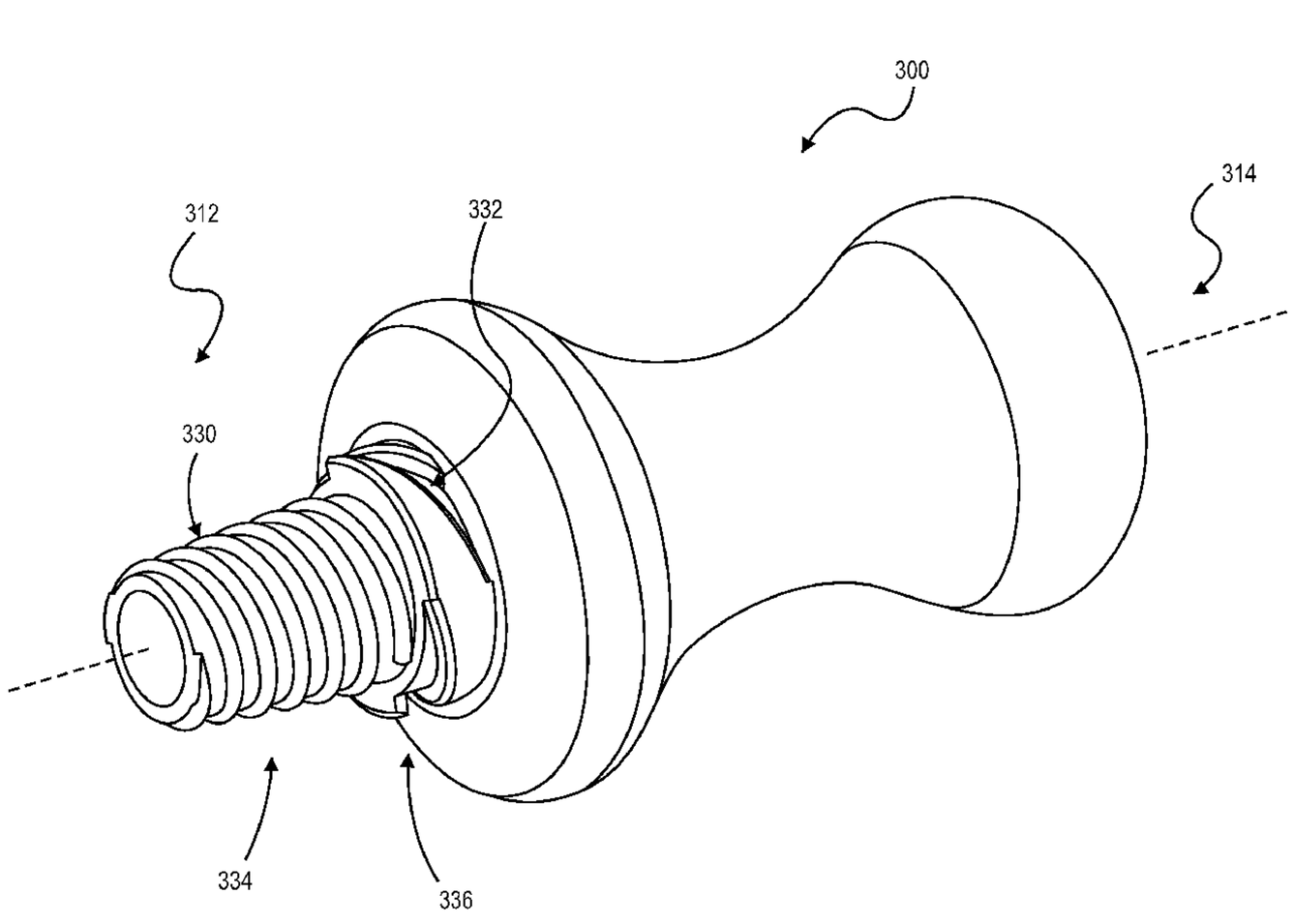
(Continued)

Primary Examiner — Lauren P Farrar
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

Apparatus and techniques for securing a medical device with hemostasis valve are described.

21 Claims, 5 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,693,031	A *	12/1997	Ryan	A61B 17/3496 604/167.03
5,902,274	A	5/1999	Yamamoto et al.	
5,916,199	A	6/1999	Miles	
5,947,931	A	9/1999	Bierman	
5,989,223	A	11/1999	Chu et al.	
6,001,081	A	12/1999	Cohen Justin	
6,113,577	A	9/2000	Hakky et al.	
6,165,168	A	12/2000	Russo	
6,287,280	B1	9/2001	Lampropoulos et al.	
7,198,066	B2	4/2007	Kagenow	
7,553,326	B2	6/2009	Sweet	
8,361,020	B2	1/2013	Stout	
8,911,396	B2	12/2014	Gordon	
9,540,398	B2	1/2017	KC et al.	
9,943,677	B2	4/2018	Gordon et al.	
2001/0053895	A1	12/2001	Vaillancourt	
2002/0087108	A1	7/2002	Maginot et al.	
2002/0107479	A1	8/2002	Bates et al.	
2004/0024381	A1	2/2004	Kurth et al.	
2004/0087905	A1	5/2004	Breznock et al.	
2004/0153021	A1	8/2004	Osborne et al.	
2005/0043684	A1	2/2005	Basta	
2005/0070546	A1	3/2005	Arrington et al.	
2005/0113799	A1	5/2005	Lenker	
2005/0165364	A1	7/2005	DiMatteo et al.	
2005/0209584	A1	9/2005	Rome	
2005/0234405	A1	10/2005	Dikeman et al.	
2006/0009737	A1	1/2006	Whiting et al.	
2006/0047266	A1	3/2006	Elkins et al.	
2006/0074398	A1	4/2006	Whiting et al.	
2006/0084927	A1	4/2006	Formichi	
2006/0129091	A1	6/2006	Bonnette et al.	
2006/0129112	A1	6/2006	Lynn	
2006/0129134	A1	6/2006	Kerr	
2007/0161956	A1	7/2007	Heuser	
2007/0167901	A1	7/2007	Herrig et al.	
2007/0225680	A1	9/2007	Biggins	
2008/0132495	A1	6/2008	Berdini et al.	
2008/0171944	A1	7/2008	Brenneman	
2008/0183183	A1	7/2008	Kida et al.	
2008/0195046	A1	8/2008	Altman	
2008/0262475	A1	10/2008	Preinitz	
2009/0264811	A1	10/2009	Asfora	
2009/0297260	A1	12/2009	Doll et al.	
2009/0306574	A1	12/2009	Kopperschmidt	
2010/0030162	A1	2/2010	Cremascoli et al.	
2010/0280063	A1	11/2010	Price et al.	
2011/0034497	A1	2/2011	Hood et al.	
2011/0190290	A1	8/2011	Hood et al.	
2012/0130151	A1	5/2012	Kassab et al.	
2012/0259292	A1	10/2012	Koehler	
2013/0006163	A1	1/2013	Gordon	
2014/0364451	A1	12/2014	John et al.	
2015/0105752	A1	4/2015	Gordon et al.	
2015/0111872	A1	4/2015	Desroy et al.	
2018/0207141	A1	7/2018	KC et al.	
2018/0214427	A1	8/2018	KC et al.	
2018/0214428	A1	8/2018	KC et al.	
2018/0214429	A1	8/2018	KC et al.	
2018/0215753	A1	8/2018	KC et al.	
2018/0221341	A1	8/2018	KC et al.	
2018/0221350	A1	8/2018	KC et al.	
2018/0221351	A1	8/2018	KC et al.	
2018/0221352	A1	8/2018	KC et al.	
2018/0221353	A1	8/2018	KC et al.	
2018/0221354	A1	8/2018	KC et al.	
2018/0222891	A1	8/2018	KC et al.	
2018/0222923	A1	8/2018	KC et al.	
2018/0228780	A1	8/2018	KC et al.	
2018/0228781	A1	8/2018	KC et al.	
2018/0228782	A1	8/2018	KC et al.	
2018/0228783	A1	8/2018	KC et al.	
2018/0228784	A1	8/2018	KC et al.	
2018/0228785	A1	8/2018	KC et al.	
2018/0230142	A1	8/2018	KC et al.	
2018/0237416	A1	8/2018	Hood et al.	
2018/0250269	A1	9/2018	KC et al.	
2018/0256588	A1	9/2018	Hood et al.	

FOREIGN PATENT DOCUMENTS

RU	2416610	4/2011
WO	WO 2001/17587	3/2001
WO	WO 2008/129385	10/2008
WO	WO2010132725	11/2010

OTHER PUBLICATIONS

European Office Action in Application No. 14853360.7, dated Dec. 14, 2016, 5 pages.

European Search Report in Application No. 14853360.7, dated Dec. 1, 2016, 4 pages.

International Preliminary Report on Patentability for PCT/US2014/060668, dated Apr. 28, 2016.

International Search Report and Written Opinion for PCT/US2014/060668 dated Jan. 28, 2015, 17 pages.

Adult Brain Tumors Treatment, National Cancer Institute, pp. 1-21 (Jan. 24, 2013), 21 pages.

Ai et al., "Optimal Method to Stimulate Cytokine Producti on and Its Use in Immunotoxicity Assessment," Int J Environ Res Public Health, Sep. 2013, 10(9):3834-3842.

Barroga et al., "Discovery of an Intra-Articular Injection Small Molecule Inhibitor of the Wnt Pathway (SM04690) As a Potential Disease Modifying Treatment for Knee Osteoarthritis," 2015 ACR/ARHP Annual Meeting, Abst. No. 2007, Sep. 29, 2015, retrieved on Sep. 27, 2018, URL <https://acrabstracts.org/abstract/discovery-of-an-intra-articular-injection-small-molecule-inhibitor-of-the-wnt-pathway-sm04690-as-a-potential-disease-modifying-treatment-for-knee-osteoarthritis/>, 3 pages.

Bass, "Why the difference between tendinitis and tendinosis matters," International Journal of Therapeutic Massage and Bodywork, vol. 5, No. 1, Mar. 2012.

Bendele, "Animal Models of Arthritis: Relevance to Human Disease" Toxicol Pathol 1999 27:134-142.

Bone fractures—https://my.clevelandclinic.org/health/diseases/15241 -bone-fractures- Jun. 2018, 5 pages.

Cancer definition in MedicineNet.com—2005, 1 page.

Cancer Drug Design and Discovery Neidle, Stephen, ed. (Elsevier/Academic Press, 2008), 5 pages.

Chanput et.al., "Transcription profiles of LPS-stimulated THP-1 monocytes and macrophages: a tool to study inflammation modulating effects of food-derived compounds," Food Funct, Dec. 2010, 1(3):254-61.

clinicaltrials.gov' [online]. ClinicalTrials.gov Identifier: NCT02095548, "Phase 1, Dose Escalation Study Evaluating the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of SM04690 in Moderate to Severe Knee Osteoarthritis (OA)," Mar. 26, 2014, [retreived on Aug. 1, 2018]. Retreived from the Internet: URL<https://clinicaltrials.gov/ct2/show/NCT02095548?term=NCT02095548&rank=1>, 7 pages.

clinicaltrials.gov' [online]. ClinicalTrials.gov Identifier: NCT02536833, "A Study Evaluating the Safety, Tolerability, and Efficacy of SM04690 Injected in the Target Knee Joint of Moderately to Severely Symptomatic Osteoarthritis Subjects," Sep. 1, 2015, [retrieved on Aug. 1, 2018]. Retrieved from the Internet: URL<https://clinicaltrials.gov/ct2/show/NCT02536833?term=NCT02536833&rank=1>, X pages.

Damia "Contemporary pre-clinical development of anticancer agents—What are the optimal preclinical models?" European Journal of Cancer 2009, 45, 2768-2781 p. 2778.

Deshmkukh et al, "Abstract: A Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Abstract from the Orthobiologic Institue (TOBI) Annual Symposium, Las Vegas, Nevada, Jun. 7, 2018, 1 page.

Deshmkukh et al, "Abstract: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Abstract from Osteoarthritis Research Society International (OARSI), Las Vegas, Nevada, Apr. 27, 2017, 2 pages.

(56) **References Cited**

OTHER PUBLICATIONS

Deshmkukh et al, "Abstract: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Abstract from the World Congress on Osteoporosis Osteoarthritis and Musculoskeletal Disease, Florence, Italy, Mar. 23, 2017, 2 pages.
Deshmkukh et al, "Abstract: Experimental Tendinopathy Treatment with SM04755, a Topical Small Molecule Inhibitor of the Wnt Pathway," Abstract from Osteoarthritis Research Society International (OARSI), Liverpool, England, Apr. 26, 2018, 3 pages.
Deshmkukh et al, "Abstract: Experimental Tendinopathy Treatment with SM04755, a Topical Small Molecule Wnt Pathway Inhibitor," Abstract from the Orthobiologic Institue (TOBI) Annual Symposium, Las Vegas, Nevada, Jun. 7, 2018, 2 pages.
Deshmkukh et al, "Poster: A Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Poster from the Orthobiologic Institue (TOBI) Annual Symposium, Las Vegas, Nevada, Jun. 7, 2018, 1 page.
Deshmkukh et al, "Poster: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Poster from the World Congress on Osteoporosis Osteoarthritis and Musculoskeletal Disease, Florence, Italy, Mar. 23, 2017, 1 page.
Deshmkukh et al, "Poster: Experimental Tendinopathy Treatment with SM04755, a Topical Small Molecule Wnt Pathway Inhibitor," Poster from the Orthobiologic Institue (TOBI) Annual Symposium, Las Vegas, Nevada, Jun. 7, 2018, 2 pages.
Deshmkukh et al, "Presentation: Experimental Tendinopathy Treatment with SM04755, a Topical Small Molecule Inhibitor of the Wnt Pathway," Presentation from Osteoarthritis Research Society International (OARSI), Liverpool, England, Apr. 26, 2018, 17 pages.
Deshmukh et al, Abstract #EULAR-6427: "Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Abstract from Annual European Congress of Rheumatology (EULAR), Madrid, Spain, Jun. 14, 2017, 2 pages.
Deshmukh et al, "Abstract #THU0522: Experimental Tendinopathy Treatment with SM04755, a Topical Small Molecule Inhibitor of the Wnt Pathway," Abstract from Annual European Congress of Rheumatology (EULAR), Amsterdam, Netherlands, Jun. 13-16, 2018, 2 pages.
Deshmukh et al, "Abstract: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Abstract from Regenerative Medicine and Biology From Development to Regeneration, St. Louis, Missouri, May 4, 2017, 2 pages.
Deshmukh et al, "Abstract: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Abstract from Orthopaedic Research Society Annual Meeting, New Orleans, Louisiana, Mar. 19, 2017, 1 page.
Deshmukh et al, "Abstract: Experimental tendinopathy treatment with SM04755, a topical small molecule inhibitor of the Wnt pathway," Abstract from Orthopaedic Research Society Annual Meeting, New Orleans, Louisiana, Mar. 10, 2018, 2 pages.
Deshmukh et al, "Poster # 1459: Experimental tendinopathy treatment with SM04755, a topical small molecule inhibitor of the Wnt pathway," Poster from Orthopaedic Research Society Annual Meeting, New Orleans, Louisiana, Mar. 19, 2018, 1 page.
Deshmukh et al, "Poster #443: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Poster from Osteoarthritis Research Society International (OARSI), Las Vegas, Nevada, Apr. 27, 2017, 1 page.
Deshmukh et al, "Poster #SAT067: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Poster from Annual European Congress of Rheumatology (EULAR), Madrid, Spain, Jun. 14, 2017, 1 page.
Deshmukh et al, "Poster #THU0522: Experimental Tendinopathy Treatment with SM04755, a Topical Small Molecule Inhibitor of the Wnt Pathway," Poster from Annual European Congress of Rheumatology (EULAR), Amsterdam, Netherlands, Jun. 13-16, 2018, 1 page.
Deshmukh et al, "Poster: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Poster from Regenerative Medicine and Biology From Development to Regeneration, St. Louis, Missouri, May 4, 2017, 2 pages.
Deshmukh et al, "Presentation: Discovery of a Small Molecule Inhibitor of the Wnt Pathway (SM04755) as a Potential Topical Treatment for Tendinopathy," Presentation from Orthopaedic Research Society Annual Meeting, New Orleans, Louisiana, Mar. 19, 2017, 19 pages.
Deshmukh et al., "A small-molecule inhibitor of the Wnt pathway (SM04690) as a potential disease modifying agent for the treatment of osteoarthritis of the knee," Osteoarthritis and Cartilage, Jan. 2018, 26(1):18-27.
Deshmukh et al., "Abstract #1104: Discovery of a Small Molecule Inhibitor of the Wnt Pathway(SM04755) As a Potential Topical Treatment for Chronic Tendinopathy," Abstract from 2016 ACR/ARHP Annual Meeting, Nov. 14, 2016, 3 pages.
Deshmukh et al., "Experimental Tendinopathy Treatment with SM04755, a Topical, Small Molecule Inhibitor of the Wnt Pathway," Slides Present at #1952 at the American College of Rheumatology (ACR) Conference 2018, Chicago, Illinois, Oct. 19-24, 2018, 22 pages.
Deshmukh et al., "Experimental Tendinopathy Treatment with SM04755, a Topical, Small Molecule Inhibitor of the Wnt Pathway," Abstract of Oral Presentation at #1952 at The American College of Rheumatology (ACR) Conference 2018, Chicago, Illinois, Oct. 19-24, 2018, 2 pages.
Deshmukh et al., "Poster #1104: Discovery of a Small Molecule Inhibitor of the Wnt Pathway(SM04755) As a Potential Topical Treatment for Chronic Tendinopathy," Poster from 2016 ACR/ARHP Annual Meeting, Nov. 14, 2016, 3 pages.
Doumpas et al., "TCF/LEF dependent and independent transcriptional regulation of Wnt/b-catenin target genes" The EMBO Journal Nov. 13, 2018 1-14.
Enzo et al., "The Wnt/β-catenin pathway in human fibrotic-like diseases and its eligibility as a therapeutic target," Molecular and Cellular Therapies, 2015, 3(1), 13 pages.
Exhibit A: *Otsuka Pharmaceutical Co., Ltd.,* v. *Sandoz, Inc., Sun Pharmaceutical Industries, Ltd., Synton BV, Synthon Holding BV, Synthon Laboratories, Inc., and Synton Pharmaceuticals, Inc., and Apotex Inc. and Apotex Corp., and Teva Pharmaceuticals USA, Inc., Barr Laboratories, Inc., and Barr Pharmaceuticals, Inc.,* Decision on Appeal, 2011-1126, -1127, May 7, 2012, 33 pages.
Forestier et al., "Prevalence of generalized osteoarthritis in a population with knee osteoarthritis," Joint Bone Spine, May 2011, 78(3):275-278.
GastricMALTLymphoma—LymphomaAssociation—2011, 10 pages.
Gitter et al., "Characteristics of human synovial fibroblast activation by IL-1 beta and TNF alpha," Immunology, Feb. 1989, 66(2):196-200.
Gunther et al., "Prevalence of generalised osteoarthritis in patients with advanced hip and knee osteoarthritis: the Ulm Osteoarthritis Study," Ann. Rheum. Dis., Dec. 1998, 57(12):717-723.
Hayami et al., "Characterization of articular cartilage and subchondral bone changes in the rat anterior cruciate ligament transection and meniscectomized models of osteoarthritis," Bone, Feb. 2006, 38(2):234-243.
Ikejima et al., "Interleukin-1 induces tumor necrosis factor (TNF) in human peripheral blood mononuclear cells in vitro and a circulating TNF-like activity in rabbits," J Infect Dis, Jul. 1990, 162(1):215-23.
International Preliminary Report on Patentability for International Application No. PCT/US2017/035411, dated Dec. 4, 2018, 12 pages.
Johnson, et. al. "Relationships between drug activity in NCI preclinical in vitro and in vivo models and early clinical trials." British Journal of Cancer 2001, 84, 1424-1431.
Lala and Orucevic, "Role of nitric oxide in tumor progression: lessons from experimental tumors," Cancer and Metastasi Review, vol. 17, Mar. 1998, pp. 91-106.

(56) **References Cited**

OTHER PUBLICATIONS

Ledford "US cancer institute overhauls cell lines" Nature Feb. 25, 2016 vol. 530 p. 391.
McMahon et al, "VEGF receptor signaling in tumor angiogenesis," The Oncologist, 2005, pp. 3-10.
MedlinePlus, [online] "Cancer," [retrieved on Jul. 6, 2007]. Retrieved from the internet, URL http://www nInn.nih.govinnedlineplus/cancer.html>.
Monner et al., "Induction of lymphokine synthesis in peripheral blood mononuclear cells with phorbol ester and calcium ionophore allows precise measurement of individual variations in capacity to produce IL 2," Lymphokine Res. 1986;5 Suppl 1:S67-73.
Mora et al, "Emerging therapies for idiopathic pulmonary fibrosis, a progressive age-related disease," Nat Rev Drug Discov. Oct. 30, 2017; 16(11): 810.
Ngkelo et. al., "LPS induced inflammatory responses in human peripheral blood mononuclear cells is mediated through NOX4 and Gia dependent PI-3 kinase signaling," Journal of Inflammation, Dec. 2012, 9(1):1, 7 pages.
Ocana, A. "Preclinical development of molecular targeted agents for cancel" Nat. Rev. Clin. Oncol. 2011, 8, 200-209.
Osteoarthritis, https://www.rnayoclinic.org/diseases-conditions/osteoarthritis/diagnosis-treatrnent/drc-20351930- Sep. 2018, 8 pages.
Park et. al., "Optimized THP-1 differentiation is required for the detection of responses to weak stimuli," Inflamm Res, Jan. 2007, 56(1):45-50.
Patani and Lavoie, "Bioisosterism: A Rational Approach in Drug Design," Chem. Rev, Jul. 25, 1996, vol. 96, p. 3147-3176.
Pinedo & Slamon, "Translational Research: the role of VEGF in tumor angiogenesis," The Oncologist, 2005, pp. 1-2.
Pritzker et al., "Osteoarthritis cartilage histopathology: grading and staging," Osteoarthr. Cantil., Jan. 2006, 14(1):13-29.
Sperber et al., "Cytokine secretion induced by superantigens in peripheral blood mononuclear cells, lamina propria lymphocytes, and intraepithelial lymphocytes," Clin Diagn Lab Immunol, Jul. 1995, 24(4):473-477.
stomach cance—Mayoclinic.com—Apr. 9, 2011, 8 pages.
Types of Brain Cancer at http://www.cancercenter.com/brain-cancer/types-of-brain-cancer.cfrn (Mar. 12, 2013), 3 pages.
Types of Breast Cancer, published in breastcancer.org (Sep. 30, 2012), 1 page.
Yan et al., "Discovery of small molecule inhibitors of the Wnt/b-catenin signaling pathway by targeting b-catenin/Tcf4 interactions" Experimental Biology and Medicine vol. 242 Jun. 2017 1185-1197.
Yazici et al., "Abstract #: 312: Safety, Efficacy and Biomarker Outcomes of a Novel, Intra-Articular, Injectable, Wnt Inhibitor (SM04690) in the Treatment of Osteoarthritis of the Knee: Interim, Exploratory Analysis of Results from a Randomized, Double-Blind, Placebo-Controlled Phase 1 Study," Poster, Presented at 2015 ACR/American College of Rheumatology Annual Meeting, San Francisco CA, Nov. 6-11, 2015; Arthritis Rheumatol. 2015; 67 (suppl 10): 1 page.
Yazici et al., "Abstract #: 313: Magnetic Resonance Imaging Outcomes Using an Intra-Articular Injection (SM04690) in the Treatment of Osteoarthritis of the Knee: Interim, Exploratory Analysis of Results from a Randomized, Double-Blind, Placebo-Controlled, Phase 1 Study," Poster, Presented at 2015 ACR/American College of Rheumatology Annual Meeting, San Francisco CA, Nov. 6-11, 2015; Arthritis Rheumatol. 2015; 67 (suppl 10): 1 page.
Zhan et al., "Wnt signaling in cancel" Oncogene (2017) 36, 1461-1473.
Zheng "Small-molecule inhibitors of Wnt signaling pathway: towards novel anticancer therapeutics" Future Med. Chem. (2015) 7(18), 2485-2505.

* cited by examiner

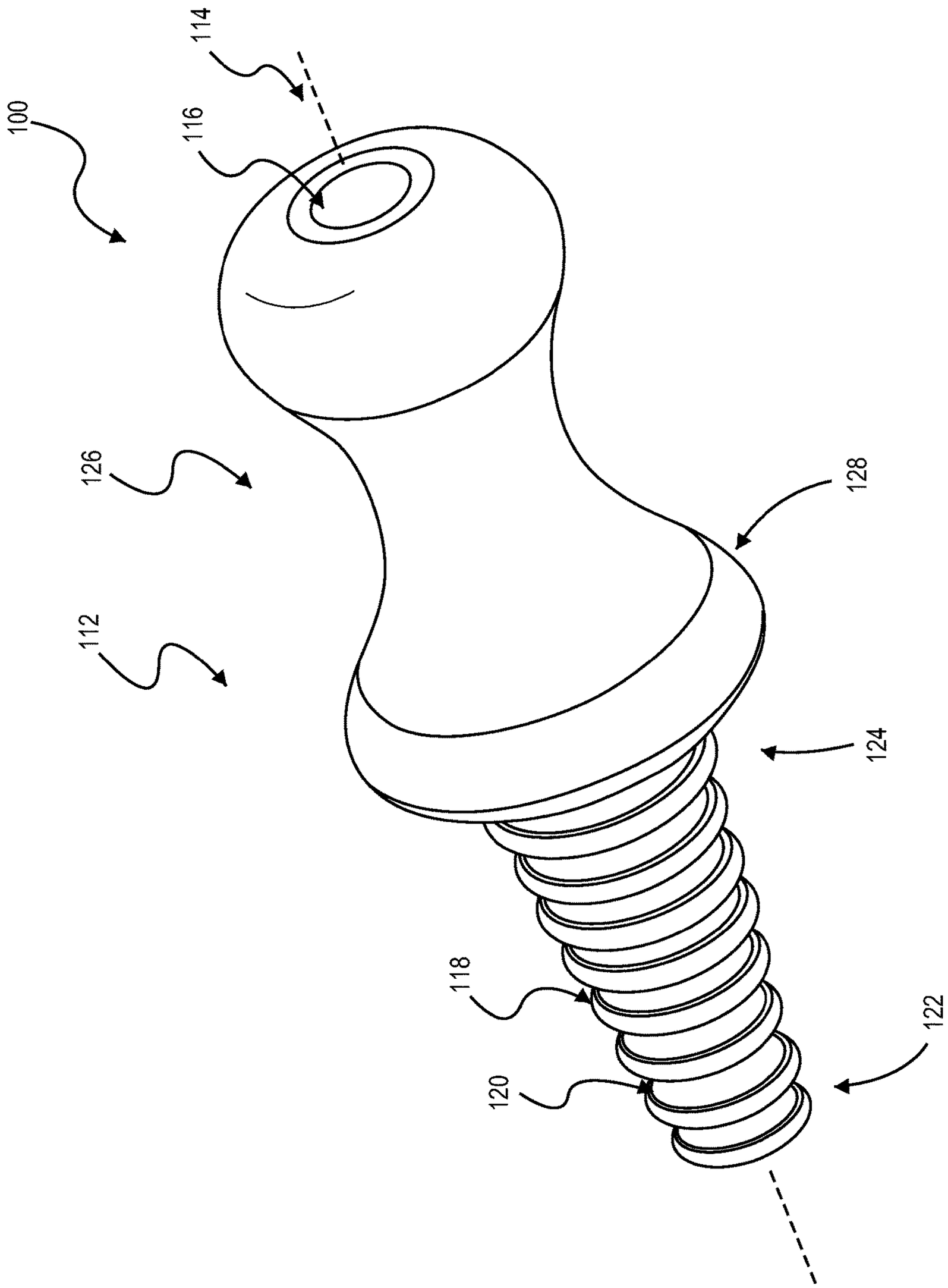


FIG. 1

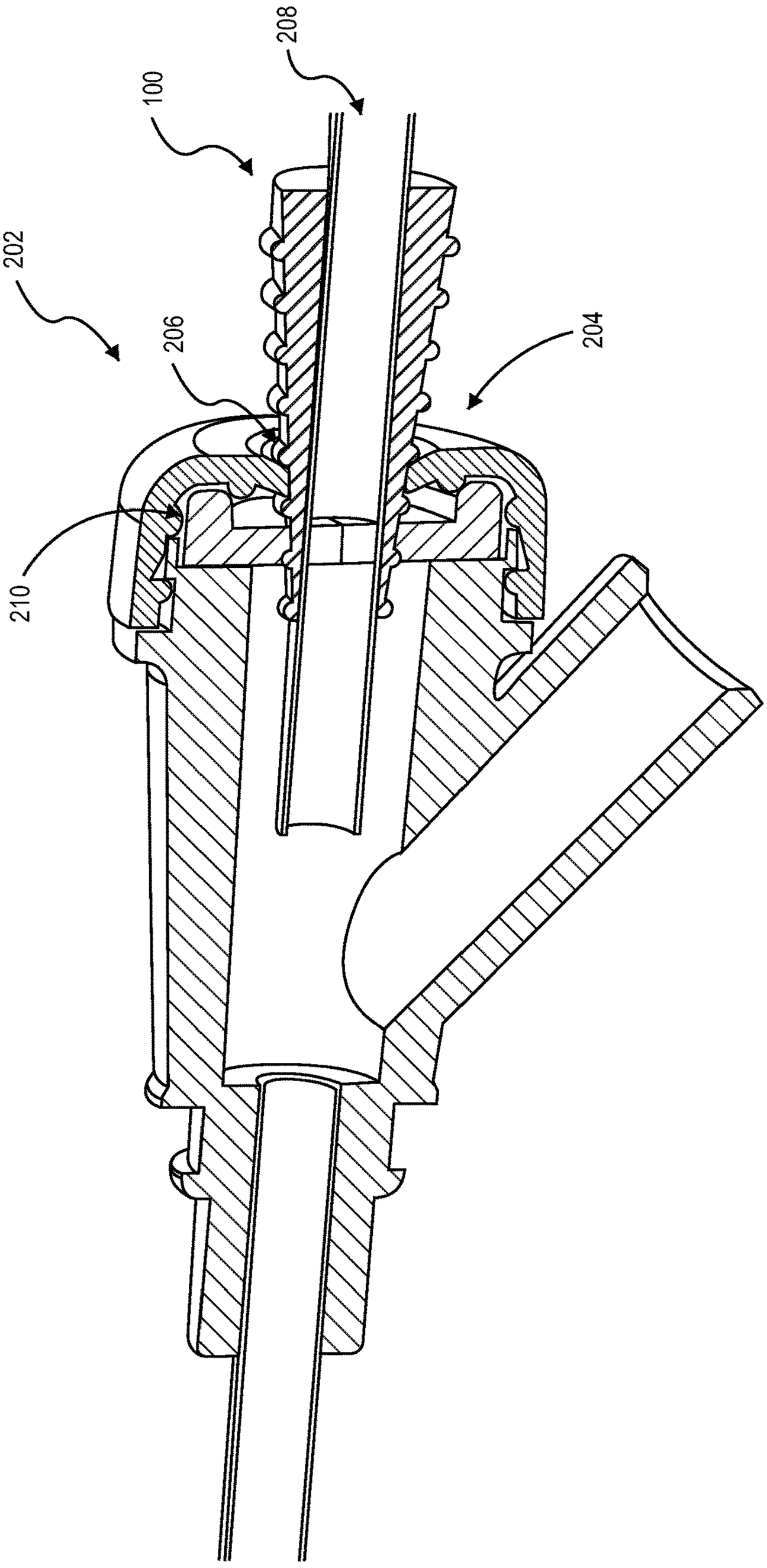


FIG. 2

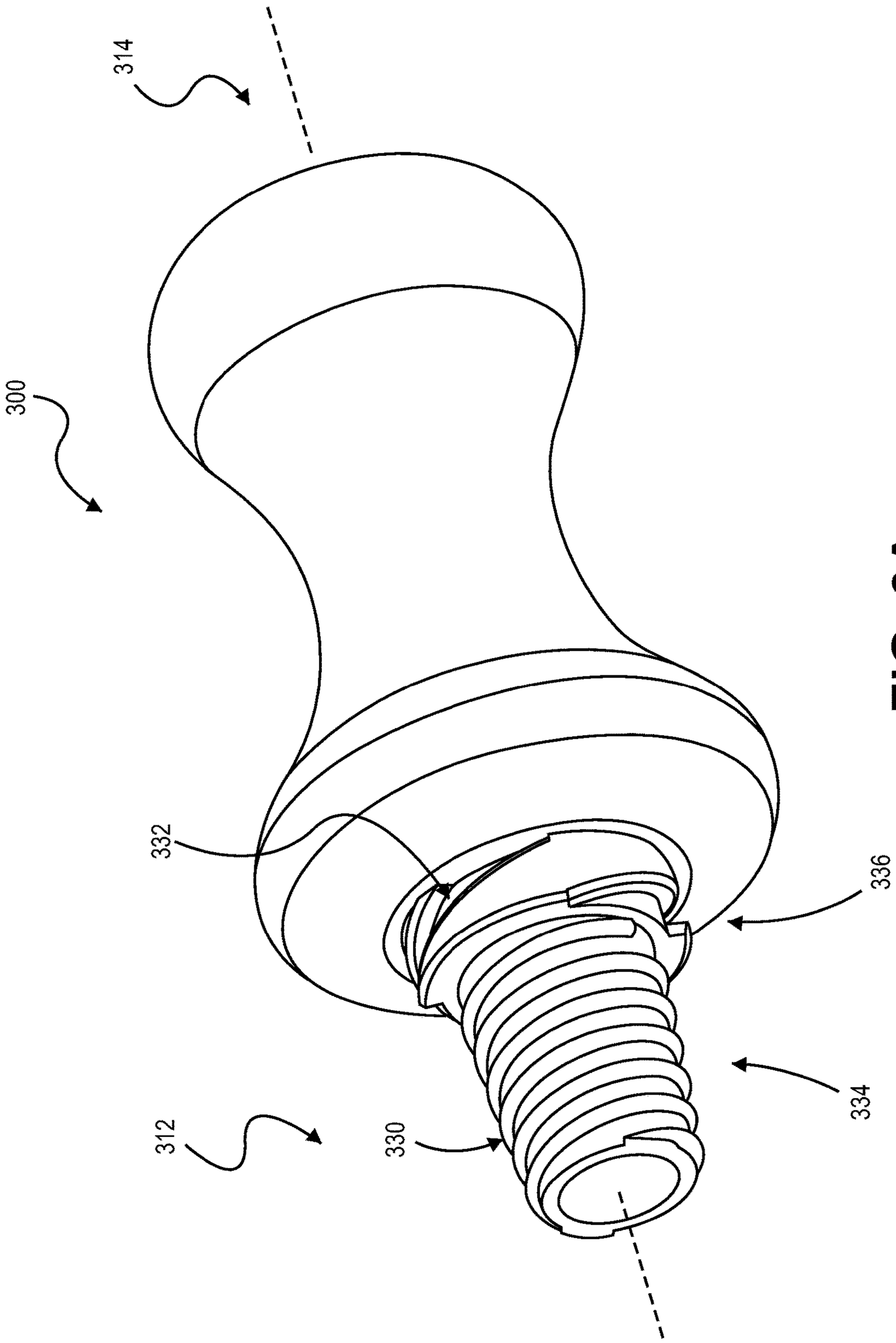


FIG. 3A

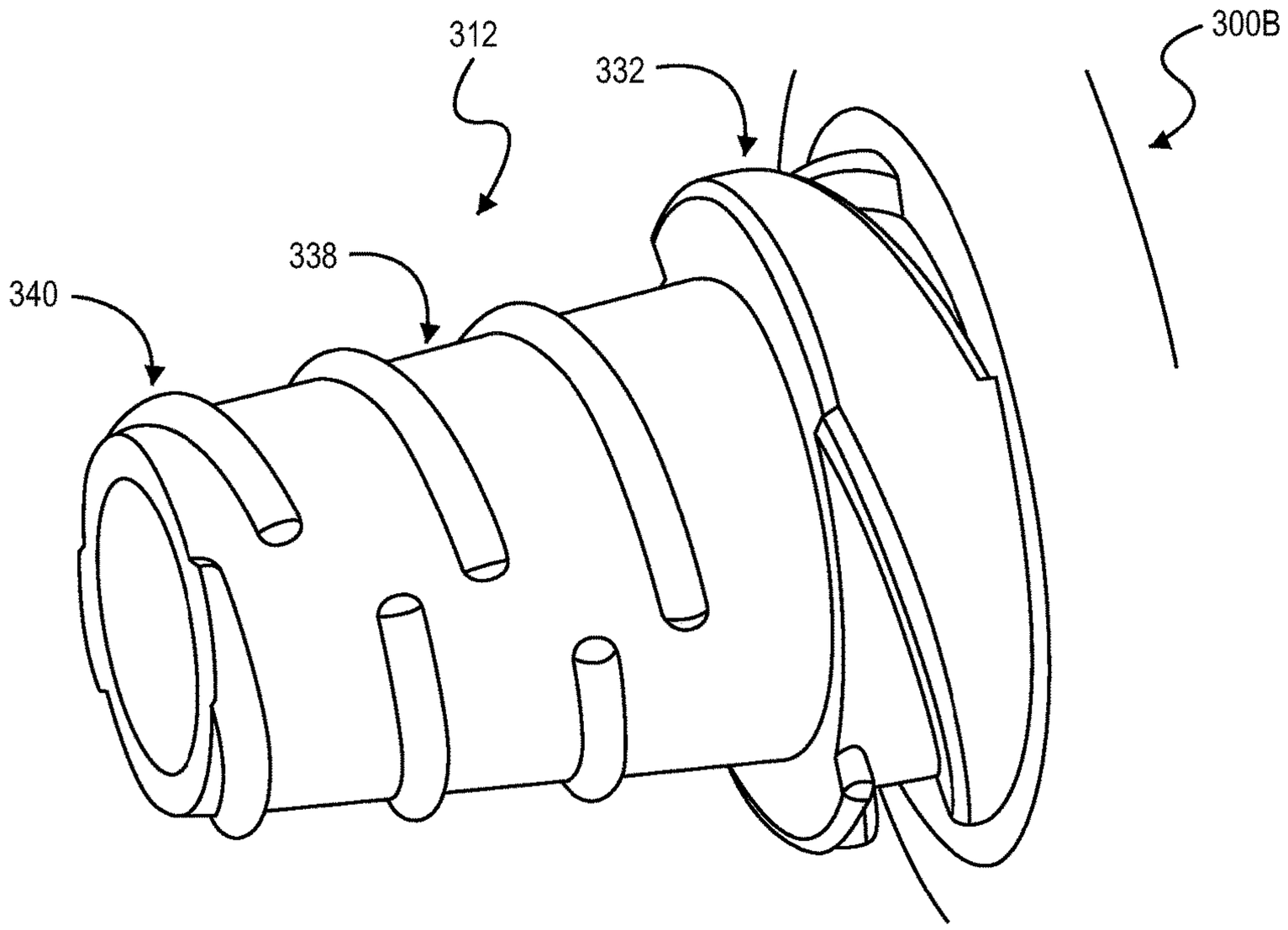


FIG. 3B

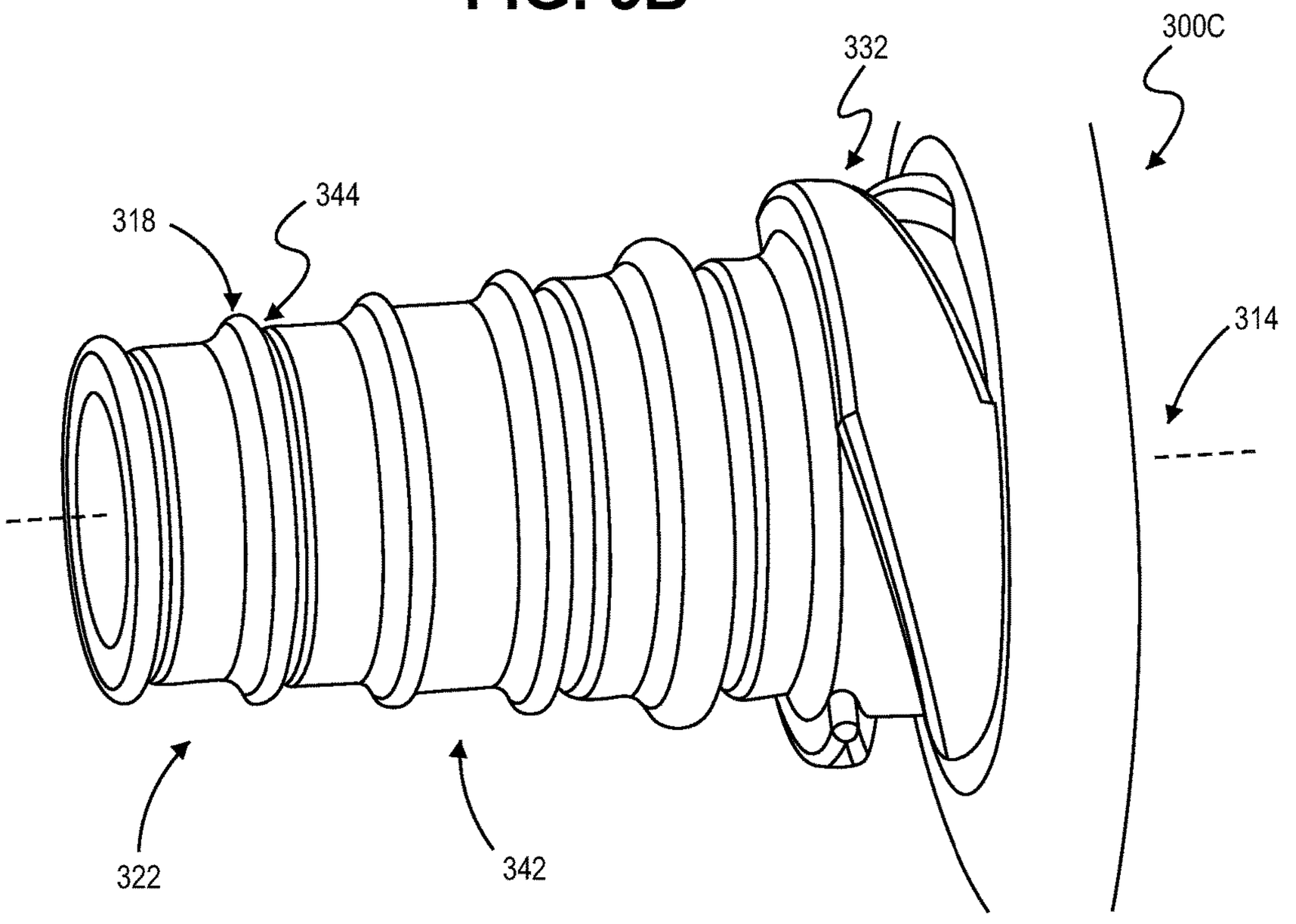


FIG. 3C

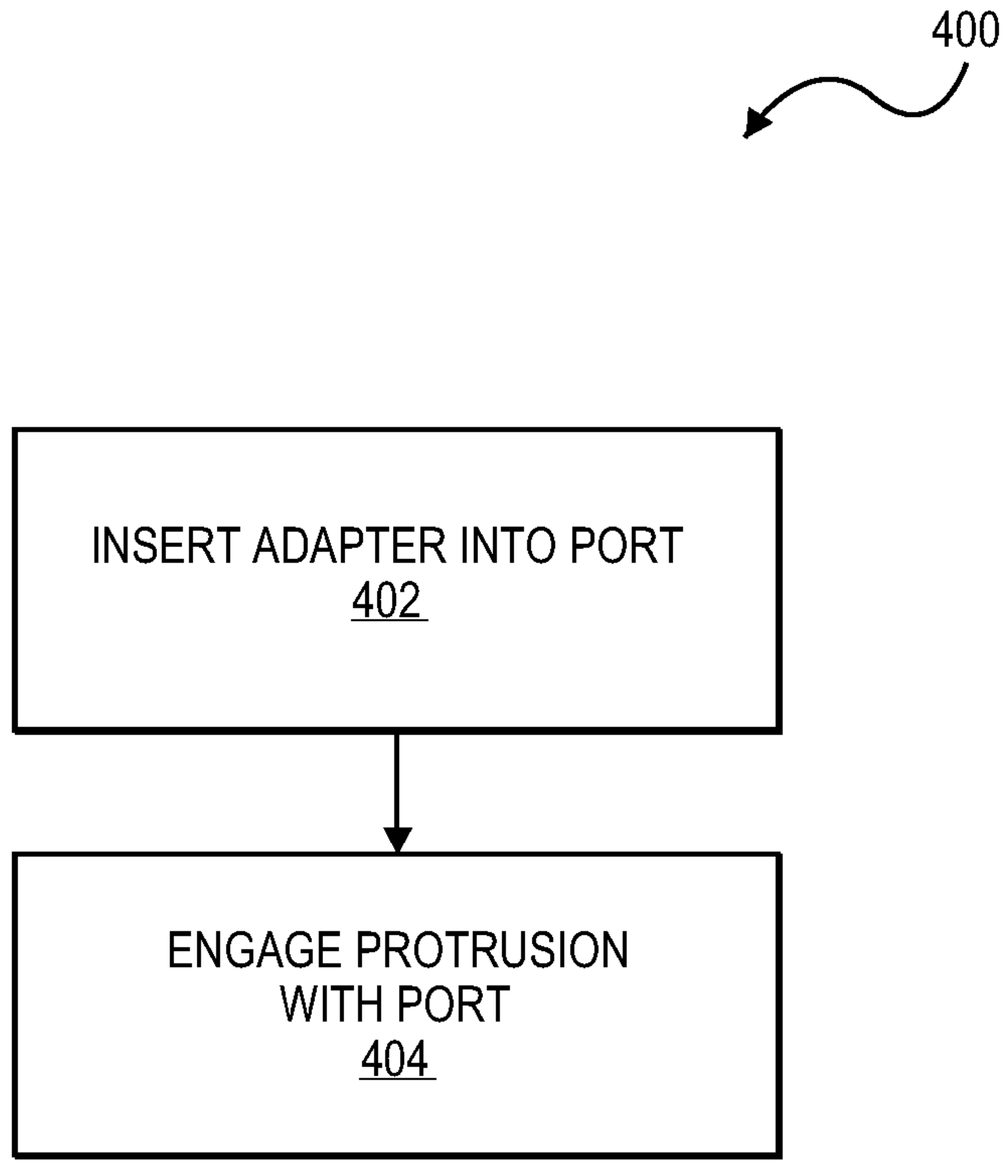

400
INSERT ADAPTER INTO PORT
402
ENGAGE PROTRUSION
WITH PORT
404

FIG. 4

SECURING A MEDICAL DEVICE TO A VALVE INSTRUMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. application Ser. No. 14/514,815, filed Oct. 15, 2014 (now U.S. Pat. No. 9,943,677), which claims the benefit of U.S. Provisional Application Ser. No. 61/891,312, filed Oct. 15, 2013. The disclosures of the prior applications are considered part of (and are incorporated by reference in) the disclosure of this application.

TECHNICAL FIELD

This disclosure relates to securing a medical device (e.g., a catheter or other elongate device) to a valve instrument (e.g., a hemostasis valve or other medical valve device). In particular embodiments, this disclosure relates to apparatus and techniques for securing a medical device and hemostasis valve together.

BACKGROUND

Hemostasis valves are used during some interventional procedures to minimize back bleeding and to prevent the introduction of air that may result in an embolism, while permitting the introduction of medicine and medical devices to blood vessels in a patient's circulatory system. For example, a hemostasis valve can be used to introduce wires, sheaths, catheters which may be equipped with balloons and lumens, and other elongate medical devices into a vein or artery. Example procedures include, but are not limited to, angiography, angioplasty and embolization procedures. In other examples, a hemostasis valve is used during a fluoroscopy procedure to introduce fluoroscopically identifiable materials, e.g., barium dye, to observe the patient's circulatory system. In some circumstances, interior portions of the hemostasis valve can be pressurized with liquid to prevent blood or gases from escaping.

Some hemostasis valves are y-shaped with three ports that are individually associated with an arm of the "y". The ports are configured as input ports for accepting a medical device or a liquid, or as an exit port through which the medical device or liquid passes into the patient's circulatory system. Other commercially available hemostasis valves include additional arms, e.g., a double-y configuration, that has an additional port for introducing a medical device or liquids through the valve and into the patient. Hemostasis valves can include a variety of valve systems to control movement of liquids, medical devices, and so on in the valve. The valve systems typically include a primary valve, such as a three-way stopcock type valve, for a standard hemostasis valve, and a variety of seals or mechanism for controlling addition/removal of medical devices and fluids. One of the ports, for example, an inlet port that is often axially align with the outlet port, can include a "twist-lock" or "push-pull lock" to control introduction of or removal of a medical device from the patient. Some elongate medical devices used with hemostasis valves can be fed or withdrawn by manipulating one of these lock devices to lock or seal the valve and then to insert or withdraw the device to target where the medicine or device is located. For example, an access sheath (having one or more guide wires therein) may be fed through an inlet port into the valve for eventual insertion into a vein.

The sizes of the inlet ports for hemostasis valves vary based on different manufacturers. Thus, although the hemostasis valve can be a particular French size indicating how large the valve is, the internal components (especially the seal devices proximate to the inlet port(s)) can be sized and configured differently between various manufacturers.

SUMMARY

Some embodiments described herein provide a universal adapter tool configured to secure an elongate medical device to an inlet port of a hemostasis valve (or other medical valve device) in a manner that provides an effect seal even when the outer size of the elongate medical device is not matched to the inlet port size of the valve device. In particular embodiments, the adapter tool can be adhered or otherwise engaged to an exterior surface of the elongate medical device so that the adapter tool provides a transition (and a sealed arrangement) between an inner valve component of a hemostasis valve and the exterior surface of the elongate medical device. In such circumstances, the adapter tool permits the elongate medical instrument to be used with a variety of hemostasis valves (or other medical valve devices) beyond the limited types of hemostasis valves that are specifically manufactured to mate with the particular size of the elongate medical instrument.

Some embodiments of an adapter tool described herein include a body portion that has a tapered body portion (e.g., a linear taper for frustoconical shape, a concave curved taper for hyperbolic conical shape, a convex curved taper for a bulbous shape, or the like) and includes one or more protrusions that extend outwardly from the tapered body portion's primary axis to engage an inlet port from any of a range of differently sized inlet ports included on hemostasis valves from different manufacturers. Each protrusion can be shaped as a ring, threading, a segment of a thread, another protruding structure, or a combination. The body portion of the adapter tool can surround a lumen of the adapter tool, which is configured to engage with an exterior surface of an elongate a medical device for passage of the elongate medical device into the hemostasis valve.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. **1** is a cross-sectional view of a system, including an adapter tool, for securing a medical device to a valve instrument, in accordance with some embodiments.

FIG. **2** is perspective view of the adapter tool of FIG. **1**, in accordance with some embodiments.

FIG. **3**A is a perspective view of an adapter tool for securing a medical device to a valve instrument, in accordance with additional embodiments.

FIG. **3**B is a perspective view of a portion of an adapter tool for securing a medical device to a valve instrument, in accordance with further embodiments.

FIG. **3**C is a perspective view of a portion of an adapter tool for securing a medical device to a valve instrument, in accordance with additional embodiments.

FIG. **4** is a flow diagram illustrating a method for securing a medical device with a valve instrument, such as a hemostasis, in accordance with some embodiments.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENT

Referring to FIGS. **1-2**, some embodiments of a medical device securement system **50** include an adapter tool **100** configured to secure an elongate medical device **220** to an inlet port **202** of a medical valve device **200** (a hemostasis valve device in this embodiment). The adapter tool **100** has a number of structural feature that cooperate to engage with elongate medical device **220** while also providing an effective seal with a valve component **210** even when the outer size of the elongate medical device **220** is not matched to the inlet port size of the valve device **200**. As described in more detail below, the adapter tool **100** can be optionally adhered or otherwise engaged to an exterior surface **222** of the elongate medical device **220** so that the adapter tool **100** provides a transition between the inner valve component **210** of the hemostasis valve device **200** and the exterior surface **222** of the elongate medical device **220**. Moreover, in this embodiment, a distal body portion **112** of the adapter tool **100** can have a tapered shaped, thereby providing a outer dimension for engaging with the inner valve component **210** that progressively increases as the insertion depth of the adapter tool **100** increases. In such circumstances, the adapter tool **100** can serve as a useful, universal adapter that permits the elongate medical device **220** to be used with a variety of hemostasis valve devices even when the hemostasis valve device **200** is not specifically manufactured to mate with the particular size of the elongate medical device **220**.

The hemostasis valve device **200** used with the adapter tool **100** can be implemented from any of a variety of proprietary designs based on the manufacturer of the valve device **200**. For example, manufacturers often produce hemostasis valve devices with differently sized inlet ports for accepting differently sized access sheaths (or other medical devices) for interventional procedures. In this example, the inlet port **202** may include a deformable seal component **210** with an opening that is configured to sealingly engage with an exterior surface of the access sheath passing through it. In some embodiments, the hemostasis valve may include multiple seal components (element **210** or having a different configuration) to ensure fluid does not escape while the sheath is inserted or removed.

As previously described, the inlet ports of various hemostasis valves can differ in size and configuration between various manufacturers, which can lead to circumstances in which the access sheath **220** (or other elongate medical device) to be used by a practitioner at a hospitals, clinic, or radiological imaging center is not sized to perfectly mate with the inlet port **202** of the selected hemostasis valve device **200**. In some embodiments, the adapter tool **100** can be beneficial used in those circumstances for securing the access sheath **220** to the inlet port **202** of the selected hemostasis valve device **200**.

Still referring to FIGS. **1-2**, particular embodiments of the adapter tool **100** can be adhered or otherwise mounted to the exterior of the elongate medical device **220** prior to distribution to the hospitals, clinic, or radiological imaging center. In such circumstances, the manufacturer of the elongate medical device **220** may bond the adapter tool **100** near a distal end **223** of the device **220** so that the adapter tool **100** is spaced apart from the distal **223** by a tip distance **110**. In such embodiments, the tip distance **110** can be selected to have a sufficient length so that a distal tip region of the medical device **220** is exposed, thereby providing the practitioner with the options of using the medical device **220** with a hemostasis valves specifically configured to mate with the outer diameter of the distal end **223** (in which case the adapter tool **100** remains external to the hemostasis device) or using the medical device **220** with the hemostasis valve **200** that is configured to mate with a larger diameter device (in which case the adapter tool **100** is inserted into to the hemostasis device **200**). Alternatively, the adapter tool **100** could being provided as a separate piece (e.g., apart from the medical device **220**), and the practitioner can subsequently adhere or otherwise engage the adapter **100** to the exterior surface **222** of the medical device **220** after determining that inlet port **202** of the hemostasis valve **200** may not match perfectly with the exterior surface **222** of the medical device **220**.

In the various embodiments in which the adapter tool **100** is used for securing the medical device **220** to the hemostasis valve device **200**, the medical device **220** and adapter tool **100** are inserted into the inlet port **202** until the seal component **210** included in the inlet port **202** contacts the tapered body portion **112** (and preferably at least one protrusion **118** that extends outwardly from the tapered body portion **112**). The adapter tool **100** and the inlet port **202** (e.g., including the seal component **210** or the inlet port **202**) can engage to form a tight seal, and preferably a liquid tight seal, by manipulating the adapter tool **100** into secure contact inside the inlet port **202**. For example, an adapter tool **100** can be press-fit or twist-fit into engagement so the hemostasis valve device **200** and the adapter **100** are secured in a relative position and thus remain stationary relative to one another during an intravascular procedure. In the embodiment depicted in FIG. **1**, the adapter tool **100** and hemostasis valve device **200** are secured in the relative position so that a longitudinal axis **105** of the adapter tool **105** is generally axially aligned with a longitudinal axis **205** of the hemostasis valve device **200**, thereby facilitating alignment of the access sheath **220** (or other elongate medical device) with the longitudinal axis **205** of the hemostasis valve device **200**.

Still referring to FIGS. **1-2**, the adapter tool **100** in this embodiment is configured to serve as a universal adapter for securing the medical device **220** to the hemostasis valve device **200**. As such, the adapter tool **100** can be configured to fit a range of hemostasis valve devices. For example, the adapter tool **100** can be configured to fit hemostasis valve devices from a variety of manufacturers having a range of differently sized inlet ports included on such valve devices. The inlet ports can range in size and configuration based on manufacturer design. In particular, the inlet port may define an opening that is a predetermined size, e.g., a particular French size, but has a specific configuration that is proprietary to the manufacturer. The opening of the inlet port can be designed for a particular purpose, such as a type of procedure, or designed to accommodate a type of medical device. The adapter tool **100**, however, can be mounted to the elongate medical device **220** so that it can be conveniently used with the hemostasis valve device intended for a different type or different size of medical device.

As shown in FIG. **1**, the depicted example of the hemostasis valve device **200** may include an inlet port **202** with one or more seal components (e.g., inner seal component **210** and cap component **215** in this embodiment). The cap component **215** includes an opening **216** that allows the elongate medical device **220** to move into or out of the hemostasis valve **202**. In this example, the opening **216** of

the cap component **215** can comprises polyisoprene or silicone rubber material, which thereby provides a sealing engagement with the device (e.g., the adapter tool **100** in this embodiment) engaged with the wall of the opening **216**. Additionally or alternatively, the inner seal component **210** can provide a flexible seal interface with the device (e.g., the adapter tool **100** in this embodiment) engaged with the component **210**. Also, the inlet region of the hemostasis valve device **200** can be configured with different locking mechanisms, such as twist-locks or push-pull locks for locking the position of the adapter tool **100**/medical device **220**. It should be understood from the description herein that other embodiments of the hemostasis valve device **200** can employ other types of valve components to prevent blood drawback while permitting insertion/retraction of adapter tool **100** during a procedure.

As shown in FIG. **2**, the adapter tool **100** can be used with a variety of medical devices, sheath-type medical devices, e.g., extenders, or other elongate medical devices that are used with a hemostasis valve. Example medical devices include catheters (including mini-catheters), probes, guide wires, lumen instruments, and other intravascular devices. Medical devices of this type can be inserted into a patient through the hemostasis valve device **200** or other device configured to offer hemostasis valve functionality. For example, an access sheath **220** (which can be used to advance one or more guide wires therethrough) is inserted into the hemostasis valve **202** during an intravascular procedure as illustrated in FIG. **1**. In this way, a physician can insert or retract the guide wires into a vein or artery while maintaining a fluid seal.

Referring to FIG. **2**, the adapter tool **100** can includes a body portion **112** with a generally tapered shape. For example, the tapered shape may be at least partially defined by a linear slope to provide a frustoconical shape. In another example, the tapered shape may be at least partially defined by a curved slope, such as a concave slope to provide a hyperbolic conical shape or a convex slope to provide a bulbous shape. The extent to which the body portion **112** tapers relative to the longitudinal axis **105** can be selected according to a number of factors. For example, the body portion **112** may have proportions (e.g., slope or length in comparison to its radius) based on the range of openings into which it may be inserted, internal fluid pressure, opening size, size of an expected medical device, expected sheath size, and so forth. For example, a body portion with a long length in comparison to the radius of its base may not secure as well in comparison to a body portion with a larger diameter end radius in comparison to its length.

The body portion **112** can be axially aligned with the longitudinal axis **105** of the adapter tool **105**, which may extends through its center along its maximum length. In some embodiments, the axis **105** is generally perpendicular to the base radius of the body portion **112**. Also, the body portion **112** may at least partially define a passage **116** that extends along the axis **105**. For example, the passage **116** can be configured to accept different sized sheaths of other elongate medical instruments. In some embodiments, the interior wall **117** of the passage **116** can comprise a material (such as a flexible silicone) that is configured to deform slightly to accept a sheath device **220** while permitting the wall **117** of the passage **116** to form a tight seal around the sheath device **220**, e.g., a fluid tight seal.

In some implementations described herein, the adapter tool **100** is adhesively connected to the sheath device **220** or other elongate medical device using, for example, a medical grade adhesive. The adhesive can form a seal (or supplement the seal) between the exterior surface **222** of the sheath device **220** and the wall **117** of the central passage **116**. A manufacturer, wholesaler, retailer, or other intermediary may fixedly secure the adapter tool **116** to the medical device **220** so the medical device **220** can be provided as a unit, e.g., a prepackaged sterile unit (having the adapter tool **100** mounted thereon) that is ready for end use. Alternatively, the adapter tool **100** can be configured to slidably engage the sheath device **220** (free of any adhesive) during use. As previously described, the interior wall **117** of the passage **116** can comprise a material (such as a flexible silicone) that is configured to deform slightly in response to an insertion force of the sheath device **220** slidably advancing through the passage and that is configured to rest against and provide a frictional gripping force (and a sealing engagement) when the sheath device **220** comes to a stop within the passage **116**.

Referring again to FIGS. **1-2**, some embodiments of the adapter tool **100** include one or more protrusions **118** for engaging with a component of the inlet port **202** of the hemostasis valve device **200**. The protrusions can be configured to engage with, for instance, a seal (e.g., inner seal component **210**, the cap component **216**, or the like) or a complaint wall that at least partially forms the inlet port in order to form a tight seal around the protrusion **118**. It is to be appreciated that in addition to the protrusions **118**, the sealing component(s) of the inlet port **202** can engage with, or at least partially engage with, a portion of the outer surface **120** of the body portion **112**.

In some embodiments, the protrusions **118** extend outwardly from axis **105** and the outer surface **120** of the body portion. For example, the protrusions **118** may extend radially outward from the axis **105** of the tool **100**. The body portion **112**, the protrusions, or both can be symmetric about the axis **105** or about a longitudinal plane extending along the axis **105**. As illustrated in the example in FIG. **2**, each of the protrusions **118** is shaped as a ring that protrudes beyond a major portion of the outer surface **120** of the body portion **112**. The protrusions **118** can have a variety of cross-sections (e.g., V-shaped, U-shaped), widths, and heights, depending on design preference, the range of hemostasis valves that it is to be used with, and other factors. Further, an adapter can include protrusions that have the same or different cross-sectional: shapes, widths, height, shapes, hardness, and the like. For example, a protrusion **118** forming a ring near a narrow distal end **122** of the tapered body portion **112** may have a smaller cross-section, a different height, and/or a different shape than that of a protrusion **118** that is adjacent a larger proximal end **124** of the tapered body portion **112**.

In the embodiment depicted in FIG. **2**, the protrusions **118** are axially aligned as annular rings of different diameters and axially spaced along the length of the body portion **112**. In this configuration, the individual protrusions **118** can protrude to different extents from the axis **105** (e.g., have progressively increasing overall outer diameters), although individual protrusions may extend the same radial distance from the outer surface **120** of the body portion **112** (e.g., each ring protrusion **118** in this embodiment extends ⅛-inch from the outer surface **120**). Accordingly, in such embodiments, a user can press-fit the adapter tool **100** into the inlet port **202** by pressing the adapter tool **100** (optionally, along with the medical device **220** mounted therein) inwardly towards the port **202** in a generally linear manner until one or more protrusions engage the corresponding seal component **210** of the port **202**. For example, a user may press in the adapter tool **100** until the seal component **210** comes in contact with a protrusion **118** of a particular diameter, at

which point, the adapter tool **100** is engaged so the seal component **210** deforms sufficiently to provide a sealing engagement around body portion **112**.

In the embodiments in which the protrusions **118** are formed as rings, the individual rings **118** can be spaced at uniform distances along the length of the axis **105**. Alternatively, the rings **118** may be non-uniformly spaced along the axis **105** (e.g., two or more rings may be clustered about an axial position) to afford slightly different diameters to account for manufacturing inconsistencies in the hemostasis valves, provide multiple contact points for engaging with the port, and so forth.

In addition to forming a liquid or pneumatically tight seal, the adapter tool **100** can be configured so it engages in a sufficiently tight manner to prevent the adapter tool **100** from inadvertently withdrawing from the hemostasis valve **200** during manipulation of the medical device **220**. For example, the adapter tool **100** is configured to achieve a sufficiently snug fit so normal push-pull insertion or removal of the medical device **220** can be achieved without loosening the adapter tool **100** from the hemostasis valve device **200**.

As shown in FIG. **2**, the adapter tool **100** may optionally include a grasping portion **126** that is structured to facilitate finger or hand grasping such as for insertion or removal of the adapter tool **100** to or from the hemostasis valve device **200**. In the illustrated embodiment, the grasping portion **126** is bounded by a pommel **128** that prevents or minimizes the likelihood of a user's fingers slipping when inserting the adapter in a press-fit manner. The contour of the grasping portion **126** may be selected to facilitate an insertion, engaging, or removal action. Also, in some embodiments, the grasping portion **126** has an axial length (along the axis **105**) that is greater than an axial length of the body portion **112** (which carries the protrusions **118**). The grasping portion **126** can be configured to press-fit the adapter tool **100** in a linear manner so it seats it in the port **202** or to facilitate a rotating or twisting action for threaded protrusions (described below). The grasping portion **126** can include texturing or include a surface treatment to facilitate manipulation, e.g., gloved manipulation. It is to be apparent that the grasping portion **126** may be formed of, or coated with a material to aid grasping. For example, a tacky outer layer (in comparison to other portions of the adapter) can be applied or co-formed in the grasping area.

The adapter tool **100** can be formed of a variety of biocompatible and sterilizable materials selected for performance characteristics. Characteristics include, but are not limited to, rigidity, deformability, resistance to degradation (thermal, radiation, water, light, electrical), inertness (e.g., chemically inert), resistance to contamination or microbial growth, out-gassing, and so forth. In embodiments, the adapter tool **100** is formed of a medical grade silicone or polyisobutylene, polyisoprene, or other medical grade plastic/rubber material, and copolymers thereof, and combinations thereof. In some instances, the material forming the body portion is loaded or impregnated with another material to give it a one or more physical, biological-related, or chemical properties. For example, the plastic for the body portion is infused with a radiation blocking to make resistant to x-ray that may be used in a medical procedure.

Also, each of the protrusions **118** can be formed of the same material as that of the body portion **112**. Alternatively, each of the protrusions **118** can be formed of a different material as that of the body portion **112**, in which case the protrusion may be co-molded with the body portion **112**. Each of the protrusions **118** can be formed of a mix of materials to provide a variety of characteristics, such as: deformability, heat resistance, and so on. In some instances, a coating can be provided while the protrusions and/or body portion are formed of one or more other materials. For example, a polytetrafluroethylene, e.g., Teflon, outer surface may be formed as part of a blow-molding process.

Referring now to FIG. **3**A, some embodiments of an adapter tool **300** can include a protrusion configuration that is different from the adapter tool **100** illustrated in FIGS. **1-2**. The adapter tool **300** in FIG. **3**A can be similarly configured to secure an elongate medical device to an inlet port of a medical valve device (such as the hemostasis valve device **200**). The adapter tool **300** can engage with elongate medical device **220** (FIG. **1**) while also providing an effective seal with a valve component **210** (FIG. **1**) even when the outer size of the elongate medical device **220** (FIG. **1**) is not matched to the inlet port size of the valve device **200** (FIG. **1**). As previously described, the adapter tool **300** can provide a transition between the inner valve component **210** (FIG. **1**) of the hemostasis valve device **200** (FIG. **1**) and the exterior surface **222** (FIG. **1**) of the elongate medical device **220** (FIG. **1**).

As shown in FIG. **3**A, the adapter **300** includes at least one protrusion in the form of a thread along the tapered body portion **312**. In this embodiment, a first protrusion **330** defines a first type of thread, and a second protrusion **332** defines a second type of thread. The threaded protrusions **330** and **332** are formed on different tapered regions **334** and **336**, respectively, of the body portion **312**. In other words, the first threaded protrusion **332** extends outwardly from the first tapered region **334** and the second threaded protrusion **336** extends outwardly from the second tapered region **336** to accommodate a larger sized port than that of the first tapered region **334**. As previously described, the tapered shape of each portion **334** and **336** may be at least partially defined by a linear slope or a curved slope.

The protrusions **330**, **332** provide a thread about the axis **305** of the adapter tool **300** to permit engagement by rotating or twisting the adapter tool **300** into a port. The pitch, the profile, and/or direction of the threaded protrusions **330**, **332** can be selected based on a variety of factors including, selected seating compression, torque used to engage the threading with a port to ensure a tight seal, the protrusion's rigidity/deformation characteristics, resistance to forces applied during a medical procedure (e.g., push-pull action), and so on. The threaded protrusions **330**, **332** may have similar or different characteristics. For example, the first threaded protrusion **330** may have a tighter pitch, have a narrower cross-section, and/or extend radially outward to a different extent in comparison to the second threaded protrusion.

The first protrusion **330** can have a pitch that twists in a first direction, e.g., clockwise. The second protrusion **332** can have a pitch that is opposite that of the first, e.g., twists in a counter-clockwise direction. The threaded protrusions **330**, **332** can be configured to accommodate different sized and/or types of inlet ports. For example, the first threaded protrusion **330** is configured to work with a first size range of inlet ports while the second threaded protrusion **332** is configured to work with a second size range.

The first and second threaded protrusions **330**, **332** can be configured so the adapter **300** may be inserted into a comparatively larger port without having to engage the smaller threaded protrusion, e.g., the first threaded protrusion **330**, with the port. In this configuration, the adapter **300** is inserted into the port until the port engages with the second threaded protrusion **332** (the larger protrusion) where it can be secured by twisting the adapter **300**. This allows the

adapter **300** to be secured without having to engage the first threaded protrusion **330** (the smaller protrusion). In this configuration, the user does not have to have to reverse direction from, for example, clockwise to counter clockwise to engage the second threaded protrusion. Moreover, cross-threading can be avoided. These features may be accomplished by sizing the protrusions **330**, **332** so the adapter **300** can be inserted linearly, thus bypassing the first threaded protrusion **330**, before the second threaded protrusion **332** engages with the port. Configuring the adapter tool **300** in this manner, can minimize the rotation used to seal the adapter in a larger port, and/or permit the adapter to accommodate a larger size range of ports.

Referring now to FIG. **3**B, some embodiments of an adapter tool **300**B can be equipped with threaded protrusions that are segmented. As illustrated, the threaded protrusions **340** are segmented so the protrusions **340** extend only partially around the circumference of the body portion **312**, e.g., the protrusion is non-continuous about the outer surface **338**. The protrusions **340** may be segmented to limit the rotation action that is used to engage with the port. For example, segmented protrusions **340** (one is referenced) can permit the adapter tool **300**B to be linearly inserted into a port until a protrusion **340** contacts the port's seal component and then rotated to a limited extent, e.g., a quarter-turn is used to tighten the adapter tool **300**B in the port. Constructing the adapter **300**B in this way can increase convenience, use less material, and so forth. As illustrated, a second threaded protrusion **332**, similar to that of FIG. **3**A, can be optionally included along the tapered body portion **312**.

Referring now to FIG. **3**C, some embodiments of an adapter tool **300**C can be equipped with a combination of different protrusions. In this embodiment, a series of ring shaped protrusions **318** are included on a first tapered region **342** of the tapered body portion **312** and a threaded protrusion **332** is included of a second tapered region **346** so as to accommodate a larger sized port and/or for a port that more readily accepts a threaded protrusion. As can be seen, the ring protrusions **318** are substantially similar to those illustrated and described in conjunction with FIG. **2**. As such, the adapter tool **300**C can implement two different engagement modes based on port size, e.g., press-fit for narrower ports and twist-fit for larger ports.

Optionally, the individual ring protrusions **318** can be associated with a corresponding groove **344**. For instance, a ring protrusion **318** has a corresponding groove **344** that is adjacent the ring **318** but farther along the axis **305** away from a distal end **322**. In this configuration, a seal component (e.g., inner seal component **210**) included on the inlet port **202** (FIG. **1**) can snap over the ring protrusion **318** and at least partially seal within the surface of the groove **344** to form a tight seal. Movement of the adapter/valve seal along the adapter's axis toward the narrow end can be prevented by the engaged ring **318**.

The following discussion describes methods that may be implemented in conjunction with the embodiments of the adapter tool described above. The techniques described below are independent of the structures described above, meaning that the techniques may be implemented in a variety of ways and are not necessarily limited to the structures illustrated in FIGS. **1**-**3**C.

Referring to FIG. **4**, some embodiments of a method **400** can use an adapter tool for securing a medical device to a hemostasis valve device. In some examples, the adapter tool **100**, **300**, **300**B, or **300**C can be used to provide a transition between the inner valve component of the hemostasis valve device and the exterior surface of the medical device. The method can be used to secure any of a variety of medical devices, such as those used in intravascular procedures.

Some embodiments of the method **400** may include operation **410**, which comprises engaging a medical device within a passageway defined by an adapter tool. For example, a sheath **220** or other elongate medical device can be slidably or adhesive engaged within a passage **116** of the adapter tool **100** (FIGS. **1**-**2**). As previously described, the medical device **220** can be engaged with the adapter tool prior to packaging the combination in a kit (e.g., preinstalled embodiments), or the medical device **220** can be engaged with the adapter tool **100** during the interventional procedure (e.g., at the hospital or clinic) after a practitioner determines that the medical device **200** may not fit perfectly with the inlet port **202** of the hemostasis valve.

Still referring to FIG. **4**, the method **400** may also include the operation **420**, which comprises installing a hemostasis valve in fluid communication with a blood vessel. For example, an outlet port of the hemostasis valve device **200** (FIG. **1**) may be positioned in fluid communication with a vein or artery of a patient. Additionally, the method **400** may include operation **430** in which the adapter tool is inserted into an inlet port of the hemostasis valve. As previously described, the adapter tool **100** (FIG. **1**) can be adhered or slidably engaged to an exterior surface **222** of the elongate medical device **220** to provide a sealed engagement therebetween. In those embodiment, the operation **430** would cause both the adapter tool **100** and the medical device **220** (FIG. **1**) to be simultaneously inserted into the inlet port **202** (FIG. **1**).

The method **400** may also include operation **440**, in which at least one protrusion of the adapter tool is engaged with a seal component of the inlet port of the hemostasis valve device. For example, the adapter tool may be equipped with one or more protrusions on a tapered body portion (some example illustrated in FIGS. **2**, **3**A, **3**B, and **3**C), and at least one of the protrusions can be sized to engage with a seal component of the hemostasis valve device **200** (FIG. **1**). As such, the adapter tool **100** can provide a transition between the valve component of the hemostasis valve device **200** and the exterior surface **222** of the elongate medical device **220** (FIG. **1**). In some embodiments, a threaded protrusion that extends radially outward from an adapter tool can be rotated into engagement with a seal component of the inlet port to create a liquid tight seal. The liquid tight seal can be formed by applying sufficient torque on the adapter tool so the protrusion and/or at least a portion of the tapered body portion engages with the seal component so the adapter tool is seated in the inlet port. The seal between the inlet port and the adapter tool can be caused by the thread and/or the portion of the outer surface deforming as the adapter tool is rotated into engagement. Rotation may occur in a clockwise or counter-clockwise direction. The adapter's direction of rotation may depend on, for example, the size and/or configuration of the inlet port. In other embodiments, a ring-shaped protrusion along the adapter tool can be press-fit into engagement with the valve component, as previously described. Thus, a user can press the adapter tool into engagement so one or more of the rings engage with the hemostasis valve device.

The method **400** may optionally include operation **450** in which a fluid (e.g., medical fluid) or guide wire (or other elongate instrument) is advanced through the medical device engaged with the adapter tool. For example, as previously described, the medical device **220** (FIG. **1**) can serve as an access sheath that permits

a medical fluid, and imaging fluid, guide wires, or other instruments to advance through the medical device **220** and into the blood vessel coupled to the hemostasis valve device **200**.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

What is claimed is:

1. An adapter device system comprising:

an adapter device, comprising:

a body portion having a leading connection surface configured to engage an inlet port of a valve, the body portion comprising:

a lumen defined by the body portion that extends between a first end of the body portion and a second end of the body portion,

a first threaded protrusion extending outwardly from a longitudinal axis of the body portion to engage with a component of a first valve, and

a second threaded protrusion extending outwardly from a longitudinal axis of the body portion to engage with a component of a second valve;

wherein the first threaded protrusion and the second threaded protrusion are located on the leading connection surface, wherein the first threaded protrusion extends at least partially around an exterior of the leading connection surface, and wherein the first threaded protrusion extends outwardly from the longitudinal axis to different outer diameters along a threaded pitch of the first threaded protrusion.

2. The adapter device system of claim **1**, wherein the first threaded protrusion extends continuously around an exterior of the leading connection surface.

3. The adapter device system of claim **2**, wherein the second threaded protrusion extends outwardly from the longitudinal axis to different outer diameters along a threaded pitch of the second threaded protrusion.

4. The adapter device system of claim **3**, wherein the second threaded protrusion extends continuously around an exterior of the leading connection surface.

5. The adapter device system of claim **1**, wherein the second threaded protrusion extends at least partially around an exterior of the leading connection surface.

6. The adapter device system of claim **1**, wherein the first threaded protrusion and the second threaded protrusion are located at different axial locations on the body portion.

7. The adapter device system of claim **1**, wherein at least one of the first threaded protrusion and second threaded protrusion is discontinuous along its length.

8. The adapter device system of claim **1**, wherein the first threaded protrusion has a first pitch, the second threaded protrusion has a second pitch, and the first pitch is different than the second pitch.

9. The adapter device system of claim **1**, wherein the adapter device is configured to permit engagement of the second threaded protrusion with the inlet port of the valve without rotation of the body portion in two directions.

10. The adapter device system of claim **1**, wherein the lumen is configured to receive a medical device for passage of the medical device through the body portion.

11. The adapter device system of claim **1**, further comprising a sheath attached to the adapter device.

12. The adapter device system of claim **11**, wherein an exterior surface of the sheath is attached to the adapter device.

13. The adapter device system of claim **11**, wherein the sheath is bonded to the adapter device.

14. The adapter device system of claim **1**, wherein the second threaded protrusion extends outwardly from the longitudinal axis a distance greater than the first threaded protrusion extends outwardly from the longitudinal axis.

15. The adapter device system of claim **14**, wherein the first threaded protrusion is configured to be located within the second valve device when the second threaded protrusion is engaged with the second valve device.

16. The adapter device system of claim **15**, wherein the first threaded protrusion is configured to be out of engagement with the second valve device when the second threaded protrusion is engaged with the second valve device.

17. An adapter device system, comprising:

an adapter device, comprising:

a body portion having a distal end and a connection surface proximate the distal end, the connection surface configured to engage an inlet port of a valve, comprising:

a lumen defined by the body portion that extends between a first end of the body portion and a second end of the body portion, the lumen configured to receive a medical device for passage of the medical device through the body portion and into the valve,

a first threaded protrusion on the connection surface extending outwardly from a longitudinal axis of the body portion to engage with a component of a first valve, and

a second threaded protrusion on the connection surface extending outwardly from a longitudinal axis of the body portion to engage with a component of a second valve; and

a medical device attached to the adapter device, the medical device comprising a sheath

wherein the first threaded protrusion extends at least partially around an exterior of the leading connection surface, and the first threaded protrusion extends outwardly from the longitudinal axis to different outer diameters along a threaded pitch of the first threaded protrusion.

18. The adapter device of claim **17**, where the second threaded protrusion extends outwardly from the longitudinal axis to different outer diameters along a threaded pitch of the second threaded protrusion.

19. The adapter device of claim **18**, wherein the first threaded protrusion and the second threaded protrusion are located at different axial locations of the connection surface.

20. The adapter device of claim **17**, wherein the connection surface is tapered.

21. The adapter device of claim **20**, wherein the body portion is configured to sealingly engage an exterior surface of the medical device during advancement of the medical device through the lumen of the body portion.

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